Notice of Allowability	Application No.	Applicant(s)	
	10/799,941	WELCH ET AL.	
	Examiner	Art Unit	
	ANDREW D. KOSAR	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *interviews of June 28, 2010 and July 15, 2010*.

2. ☒ The allowed claim(s) is/are *26 and 32-52*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20100628* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Julia Grimes, on July 15, 2010.

Election/Restrictions

The restriction requirement of November 15, 2005 is withdrawn to the extent the diseases IBD and cirrhosis have been rejoined.

Examiner's Amendment/ Reasons for Allowance

The application has been amended as follows:

CANCEL claims 1, 8, 17, 21, 24, 25 and 27-31.

In claim 26, line 1 REPLACE the term -- irritable -- with -- inflammatory --

ADD NEW claims 32-42 as follows:

32. The method of claim 26, wherein the secretin and the oxytocin are administered concurrently.

33. The method of claim 26, wherein the secretin and the oxytocin are administered sequentially.

34. The method of claim 26, wherein the secretin and the oxytocin are administered together in a single combined formulation.

35. The method of claim 26, wherein the secretin and the oxytocin are administered in separate individual formulations.

36. The method of claim 26, wherein the secretin or the oxytocin are administered by an oral, inhalational, parenteral, intramuscular, intraperitoneal, intravascular, intravenous, subcutaneous or transdermal route.

37. The method of claim 26, wherein the secretin is administered at a dose of from about 0.001 mg per day to about 1000 mg/day.

38. The method of claim 26, wherein the secretin is administered at a dose of from about 1 mg per day to about 100 mg/day.

39. The method of claim 26, wherein the oxytocin is administered at a dose of from about 0.001 mg per day to about 1000 mg/day.

40. The method of claim 26, wherein the oxytocin is administered at a dose of from about 1 mg per day to about 100 mg/day.

41. The method of claim 26, wherein the subject is a human.

42. A method for treating primary biliary cirrhosis in a subject, comprising administering to the subject a therapeutically effective amount of secretin and a therapeutically effective amount of oxytocin.

43. The method of claim 42, wherein the secretin and the oxytocin are administered concurrently.

44. The method of claim 42, wherein the secretin and the oxytocin are administered sequentially.

45. The method of claim 42, wherein the secretin and the oxytocin are administered together in a single combined formulation.

46. The method of claim 42, wherein the secretin and the oxytocin are administered in separate individual formulations.

47. The method of claim 42, wherein the secretin or the oxytocin are administered by an oral, inhalational, parenteral, intramuscular, intraperitoneal, intravascular, intravenous, subcutaneous route or transdermal route.

48. The method of claim 42, wherein the secretin is administered at a dose of from about 0.001 mg per day to about 1000 mg/day.

49. The method of claim 42, wherein the secretin is administered at a dose of from about 1 mg per day to about 100 mg/day.

50. The method of claim 42, wherein the oxytocin is administered at a dose of from about 0.001 mg per day to about 1000 mg/day.

51. The method of claim 42, wherein the oxytocin is administered at a dose of from about 1 mg per day to about 100 mg/day.

52. The method of claim 42, wherein the subject is a human.

The following is an examiner's statement of reasons for allowance: The closest prior art does not teach or suggest, alone or in combination, treating IBD or primary biliary cirrhosis with the combination of secretin and oxytocin. The combination of therapeutics is suggested in the art for treating autism; however one would not find suggestion or motivation to extend the use to diseases such as cirrhosis or IBD.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/
Primary Examiner, Art Unit 1654